October 2, 2020

Siesta Medical, Inc.
Michael Kolber
Vice President, Regulatory Affairs
101 Church Street, Suite 3
Los Gatos, California 95030

Re: K201238/S001
Trade/Device Name: Encore System
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: ORY
Dated: August 31, 2020
Received: September 3, 2020

Dear Michael Kolber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201238

Device Name

Encore™ System

Indications for Use *(Describe)*

The Encore System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of obstructive sleep apnea (OSA) and / or snoring.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number	K201238	
Submitter Name and Address		
Name	Siesta Medical, Inc.	
Contact	Michael Kolber Vice President, Regulatory Affairs	
Address	101 Church Street, Suite 3 Los Gatos, CA 95030	
Telephone	408-505-6626	
Fax	408-399-7600	
Date Prepared	August 31, 2020	
General Device Information		
Product Name	Encore™ System	
Common Name	Intraoral device for snoring and obstructive sleep apnea	
Classification	21CFR872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.	
Device Class	Class II	
Product Code	ORY	
Primary Predicate Device Manufacturer	**Device Name**	**510(k) Number**
Siesta Medical, Inc.	Encore System	K183310
Reference Predicate Device Manufacturer		
Teleflex Medical, Inc	Force Fiber Suture	K063778
Device Description		
The Encore System is designed for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone and hyoid bone suspension to the mandible bone using a bone screw and suspension lines. The Encore System consists of 1) an integrated suture passer pre-loaded with size #2-0 braided polyester suture, 2) three (3) bone screws and two (2) bone screw inserters, 3) a suspension line lock tool, 4) a threading tool, and 5) a drill bit. In addition, a #2 braided polyethelene suspension line is provided. All components are provided sterile.		
Intended Use (Indications)		
The Encore System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of obstructive sleep apnea (OSA) and /or snoring.		
Comparison to the Predicate Device		
The Encore System is now available with #2 braided polyethylene suspension line. It has the same intended use as the predicate device.		

The fundamental scientific technology and technological characteristics of the Encore System are the same as the predicate device including mechanism of action, packaging, biocompatibility, sterilization, and labeling. The Encore System now includes a #2 braided polyethylene suspension line and a drill bit.
Summary of Non-Clinical Testing Performance testing was conducted to confirm that the #2 braided polyethelene suspension line has sufficuent strength to suture strength to resist breakage. A Suture Tensile Strength Test was conducted to determine the amount of force applied to the suture until the suture breaks. The results of this test confirmed that the strength of the #2 braided polyethylene suspension is similar to that of the existing #2 braided polyester suspension line.
Conclusion
Based on the intended use and technological characteristics together with results from the non-clinical performance testing, we believe that the subject device Encore System is substantially equivalent to the predicate device K183310.